



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventor(s): Richard J. Schultz  
Application No.: 10/749,755  
Confirmation No.: 6187  
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Examiner: Mark Spisich  
Art Unit: 1744  
Last Office Action: May 5, 2005  
Title: **SURGICAL INSTRUMENT  
CLEANING BRUSH**

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on August 5, 2005.

August 8, 2005  
(Date of deposit)

**Elaine Checovich**

Elaine Chesser  
(Signature)

August 3, 2005  
Date of Signature

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 CFR 1.132**

Dear Sir:

**The undersigned declares as follows:**

1. My name is Richard J. Schultz. I am currently the President of Spectrum Surgical Instruments, Inc. ("SSIC"). I have been the President of SSIC since 1986.
2. I am the inventor of the invention described in the above-captioned patent application and am familiar with it.
3. I am familiar with the marketplace for surgical instruments and have been familiar with it for the past 19 years.
4. SSIC began selling surgical instrument cleaning brushes many years ago in the United States. These brushes were sold individually or as kits. Some of these surgical instrument cleaning brushes were made of two stainless steel helical segments which were wound tightly into a double helix. Bristles were captured between the two helical segments. The bristles were located at one end of the brush. A circular loop

was located at the other end of the brush. The bristles did not have anti-bacterial or anti-microbial properties.

5. These surgical instrument cleaning brushes without anti-bacterial or anti-microbial properties had the following unit sales and gross receipts for the years given in the following table:

Year	Unit Sales (# brushes)	Gross Receipts
2001	99,064	\$664,522
2002	103,950	\$697,295

6. Prior to about January 2003, many surgical instrument cleaning brushes were cleaned or sterilized by being soaked in a disinfectant solution, then placed in an ultrasonic cleaning machine. The brush itself was cleaned in order to prevent cross-contamination between instruments which might be caused by using a non-sterile brush. The brush would be cleaned between every use. Alternatively, the brush was discarded after one use.

7. To the best of my knowledge, prior to about January, 2003, a surgical instrument cleaning brush having bristles with anti-bacterial or anti-microbial properties was unknown in the United States.

8. Many surgical instrument cleaning brushes have restricted spaces between adjacent bristles which are difficult to clean. One of the major reasons, if not the major reason, for using a surgical instrument cleaning brush is to facilitate the removal of bacteria and other microbes from a surgical instrument. There has been a need for brushes with improved cleaning and sterilizing ability for many years. The ongoing need for improved sterilization of surgical instruments has been illustrated over the years by the widespread use of disposable (one use) instruments, the continued offering of improved and expensive sterilization equipment every few years, and reports in the popular press concerning the incidence of infections in hospitals.

9. On or about January 2003, SSIC began selling surgical instrument cleaning brushes having bristles with anti-bacterial and/or anti-microbial properties in the United States. They differed from previous surgical instrument cleaning brushes only in that the bristles had anti-bacterial and/or anti-microbial properties.

10. These surgical instrument cleaning brushes with anti-bacterial and/or anti-microbial properties were an immediate success and had the following unit sales and gross receipts for the years given in the following table:

Year	Unit Sales (# brushes)	Gross Receipts
2003	148,500	\$996,000
2004	198,000	\$1,294,000
2005	257,400	\$1,695,000 (projected)

11. No extensive advertising was conducted on the brushes with anti-bacterial and/or anti-microbial properties. The products were described in SSIC's catalog, on SSIC's website, and at professional meetings.

12. In my opinion, the commercial success of the brushes with anti-bacterial and/or anti-microbial properties is due solely to their having anti-bacterial and/or anti-microbial properties. Potential users of these brushes, upon being exposed to their anti-bacterial properties, immediately realize that this property addresses their need for an improved brush.

13. The commercial success of the brushes with anti-bacterial and/or anti-microbial properties and the long-felt but unmet need for such brushes attest to the non-obviousness of the subject matter disclosed in the above-captioned application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

By \_\_\_\_\_

Printed Name: Richard J. Schultz

Date: 8-5-05